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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/444,507	11/22/1999	ANDREW L. DIRIENZO	VPR-001US	8746

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[REDACTED] EXAMINER

BLECK, CAROLYN M

ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 08/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/444,507	DIRIENZO, ANDREW L.
Examiner	Art Unit	
Carolyn M Bleck	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 16 June 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

4) Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-19 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 16 June 2003 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the CPA filed 16 June 2003. Claims 1-19 are pending. Claim 19 is newly added. Formal Drawings filed 16 June 2003 have been entered and considered.

Drawings

2. The corrected or substitute drawings were received on 16 June 2003. These drawings are approved by the Examiner.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-3 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Under the statute, the claimed invention must fall into one of the four recognized statutory classes on invention, namely, a process (or method); a machine (or system); an article of manufacture; or a composition of matter.

(A) Claims 1-3 appear to be directed toward a patient record. However, it is unclear as to which recognized statutory class of invention the a patient record of claim 1 is directed. In particular, a patient record is not a process or method as it lacks a series of

steps. A patient record is not a machine or system as there is no specific recitation of machine or system components. A patient record is not recognized as a composition of matter. A patient record, per se, is merely a collection of data.

Under the guidance of recent case law, the requirements of 35 U.S.C. 101 are met when "the practical application of the abstract idea produces a useful, concrete, and tangible result" (State Street Bank & Trust Co. vs. Signature Financial Group, Inc., 47 USPQ2d 1596, 1601-02 (Fed. Cir. 1998)). However, the claims, as presently recited, do not appear to have a tangible result. Data structures or computer programs, in general, that are not claimed as embodied in computer-readable media are descriptive material per se, and are not statutory because they are not capable of causing functional change in a computer.

In particular, it is unclear whether the patient record, as recited in claims 1-3, is embodied on a specific readable medium within the technological arts (and thus tangible), since it appears the patient record is not limited to any particular structural element. Such claimed data does not define any structural and functional interrelationships between the data and a system for maintaining the data, which permit the purpose of the data to be realized (see MPEP section 2106 section IV, B, 1, (a) for further guidance). Simply stated, how is the claimed patient record tangibly embodied within a system and how is that embodiment structurally related to the clinical support system?

In light of the above, it is respectfully submitted that the claimed invention, although useful and concrete, is not tangible, and thus fails to recite the practical application of an abstract idea to satisfy the requirements of 35 U.S.C. 101.

(B) Claims 2-3 incorporate the deficiencies of claim 1 through dependency, and are therefore, rejected as well.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-5, 7, 9-12, 14-16, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eberhardt (5,832,488) in view of Garcia (5,065,315) as cited in the previous Office Action (paper number 2), for substantially the same reasons given in the prior Office Action (paper number 2). The reasons appear hereinbelow.

(A) As per claim 1, Eberhardt discloses a patient medical record comprising:

(a) an electronic critical information file containing critical medical information about an individual (col. 7 lines 54-61).

Eberhardt fails to expressly disclose using a hardcopy patient record to store routine and essential information, wherein the information in the electronic critical information file takes precedence over the hardcopy patient record.

Garcia discloses a computer system for hospital records management, wherein a paper patient chart is used to store and report patient information such as medical data, test results, scheduling information, and important documents (col. 1 lines 13-55, col. 3 line 58 to col. 4 line 4, col. 10 lines 1-5, and col. 31 lines 50-52), and wherein information in the electronic patient record is first entered through a computer and then printed for inclusion in the patient record (col. 6 line 1 –18 and col. 32 line 10-13 and 33-38).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Garcia within Eberhardt's patient record with the motivation of allowing a health care specialist to quickly ascertain important facts about a patient using the critical information file, such as in an emergency (Eberhardt, col. 7 lines 56-60), and increasing the efficiency and reducing the paperwork required to update a paper patient chart (Garcia, col. 2 lines 23-28).

(B) As per claim 2, Eberhardt discloses a patient medical record, wherein the patient medical record is comprised of a printout of the critical information file (Fig. 2, col. 7 lines 54-60, and col. 9 lines 28-30). Eberhardt fails to expressly disclose a patient medical record, wherein a hardcopy of the patient medical record is stored in a

designated storage area, and wherein a printout of the critical information file is added to the hardcopy of the patient record each time the hard copy is retrieved from storage.

Garcia discloses a computer system for hospital records management, wherein the paper patient chart is stored in a warehouse (col. 10 lines 1-5), and wherein a documented copy of patient information recorded electronically is included within each paper patient chart when the chart is retrieved from storage (col. 6 lines 10-12 and col. 32 lines 33-38).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Garcia within Eberhardt's patient record with the motivation of providing accurate, up to date, medical information (Eberhardt, col. 3 lines 26-30), and more efficiently and easily displaying patient information (Garcia, col. 2 lines 23-47). The motivation for combining Garcia with Eberhardt is given above in claim 1, and incorporated herein.

(C) As per claim 3, Garcia discloses a computer system for hospital records management, wherein a documented copy of patient information recorded electronically is used to request the paper patient chart be retrieved from long term storage (col. 5 lines 43-53 and col. 10 lines 2-5). The remainder of claim 3 repeats the same limitations of claim 2, and is therefore rejected for the same reasons given for claim 2, and incorporated herein. The motivation for combining Garcia with Eberhardt is given above in claim 1, and incorporated herein.

(D) As per claim 4, Eberhardt discloses a method for medical records management comprising:

- (a) creating a critical information file for each patient (col. 7 line 54 to col. 8 line 10, col. 10 lines 38-45, and col. 18 lines 15-18);
- (b) updating a critical information file with information such as blood type, medical conditions, allergies, sensitivities to drugs and environmental factors, and current prescriptions (col. 4 lines 54-56, col. 7 line 54 to col. 8 line 10, and col. 10 lines 38-45);
- (c) opening the critical patient information file each time the patient is examined (col. 4 lines 54-56, col. 7 line 54 to col. 8 line 10, and col. 10 lines 38-45); and
- (d) printing a copy of the critical information file (Fig. 2, col. 7 lines 54-60, and col. 9 lines 28-30).

Eberhardt fails to expressly disclose inserting a printed copy of the critical information file into the hard copy of the patient record whenever the hardcopy is accessed in the healthcare provider's office.

Garcia discloses a computer system for hospital records management, wherein the paper patient chart is stored in a warehouse (col. 10 lines 1-5), and wherein a documented copy of patient information recorded electronically is included within each paper patient chart when the chart is retrieved from storage at the healthcare provider's location (col. 6 lines 10-12 and col. 32 lines 33-38).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Garcia within Eberhardt's

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method with the motivation of allowing a health care specialist to quickly ascertain important facts about a patient, such as in an emergency (Eberhardt, col. 7 lines 56-60), providing accurate, up to date, medical information (Eberhardt, col. 3 lines 26-30), and more efficiently and easily displaying patient information (Garcia, col. 2 lines 23-47).

(E) As per claim 5, Eberhardt discloses recording information about current prescriptions (col. 7 lines 57-61).

(F) As per claim 7, Eberhardt discloses recording information about allergies (col. 7 lines 57-61).

(G) As per claims 9 and 10, Eberhardt and Garcia fail to expressly disclose a method, wherein the method taught collectively by Eberhardt and Garcia is performed by a first user at a healthcare provider's office, and a second user closes the vital patient record in the healthcare provider's office. However, Eberhardt discloses a method for medical records management, wherein a user can save and close the critical information file in the health care specialist's office (col. 7 lines 54-61 and col. 9 line 28-34). It is respectfully submitted that at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to modify the method taught collectively by Eberhardt and Garcia to include the ability to have different users open and close records with the motivation of decreasing the time and increasing the flexibility for medical staff processing patient records (Garcia, col. 1 line 35-54, and col. 2 lines 23-

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48). The motivation for combining Garcia with Eberhardt is given above in claim 1, and incorporated herein.

(H) Claim 11 differs from method claim 4 by reciting a recording medium for storing computer readable instructions. As per this element, Eberhardt discloses:

memory including random access memory (RAM) and permanent memory for storing a computer program for creating and maintaining a patient's critical information file (col. 18 line 56 to col. 19 line 14 and col. 20 lines 11-37).

The remainder of claim 11 repeats the subject matter of method claim 4, respectively as a set of computer readable instructions rather than a series of steps. As the underlying processes of claim 4 have been shown to be fully disclosed by the collective teachings of Eberhardt and Garcia in the above rejections of claim 4, it is readily apparent that the computer program stored in computer memory disclosed by Eberhardt and Garcia provides the means to carry out these steps. As such these limitations are rejected for the same reasons given above for method claim 4, and incorporated herein.

(I) Claims 12 and 14 repeat the same limitations of claims 5 and 9, and are therefore rejected for the same reasons given for those claims.

(J) Claim 15 differs from method claim 4 by reciting a computer program. As per this element, Eberhardt discloses:

a computer program for creating and maintaining a patient's critical information file (col. 5 lines 50-59, col. 18 line 56 to col. 19 line 14, and col. 20 lines 11-37).

The remainder of claim 15 repeats the subject matter of method claim 4, respectively as a set of computer readable instructions rather than a series of steps. As the underlying processes of claim 4 have been shown to be fully disclosed by the collective teachings of Eberhardt and Garcia in the above rejections of claim 4, it is readily apparent that the computer program disclosed by Eberhardt and Garcia provides the means to carry out these steps. As such these limitations are rejected for the same reasons given above for method claim 4, and incorporated herein.

(K) Claims 16 and 18 repeat the same limitations of claims 5 and 9, and are therefore rejected for the same reasons given for those claims.

7. Claims 6, 8, 13, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eberhardt (5,832,488) and Garcia (5,065,315) as applied to claims 4-5, 7, 11-12, and 15-16 above, and further in view of Sujansky ("The Benefits and Challenges of an Electronic Medical Record: Much More than a "Word-Processed" Patient Chart", *Western Journal of Medicine*, San Francisco, vol. 169, September 1998, pages 176-183) as cited in the previous Office Action (paper number 2), for substantially the same reasons given in the prior Office Action (paper number 2). The reasons appear hereinbelow.

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(A) As per claims 6 and 8, the relevant teachings of Eberhardt and Garcia, and the motivation for their combination is as discussed in the rejections above and incorporated herein.

Eberhardt and Garcia fail to expressly disclose executing a drug interaction screening program using information recorded about currently prescribed medications for a patient. Sujansky discloses a drug prescription assistance program integrated with an electronic medical records system to detect drug-drug and drug-allergy interactions based on prescription information and other clinical data (pg. 4 par. 2-3).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include Sujanksy's program within the method taught by Eberhardt and Garcia with the motivation of avoiding adverse drug reactions, inappropriate drug selections, and inappropriate dosing (Sujansky, pg. 4 par. 2-3).

(B) Claims 13 and 17 repeat the same limitations of claim 6, and are therefore rejected for the same reasons given above for claim 6, and incorporated herein.

8. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eberhardt (5,832,488) in view of Garcia (5,065,315) and Sujansky ("The Benefits and Challenges of an Electronic Medical Record: Much More than a "Word-Processed" Patient Chart", *Western Journal of Medicine*, San Francisco, vol. 169, September 1998, pages 176-183).

(A) As per claim 19, Eberhardt discloses a method for medical records management comprising:

- (a) creating a critical information file for each patient (col. 7 line 54 to col. 8 line 10, col. 10 lines 38-45, and col. 18 lines 15-18);
- (b) updating a critical information file with information such as blood type, medical conditions, allergies, sensitivities to drugs and environmental factors, and current prescriptions (col. 4 lines 54-56, col. 7 line 54 to col. 8 line 10, and col. 10 lines 38-45) (it is noted that at least 2 categories of information are recorded by Eberhardt's critical information file);
- (c) each time the patient is examined (reads on "whenever the patient interacts with the healthcare provider's office") (col. 4 lines 54-56, col. 7 line 54 to col. 8 line 10, and col. 10 lines 38-45), opening the critical patient information file each time the patient is examined (col. 4 lines 54-56, col. 7 line 54 to col. 8 line 10, and col. 10 lines 38-45);
- (d) printing a copy of the critical information file (Fig. 2, col. 7 lines 54-60, and col. 9 lines 28-30).

Eberhardt fails to expressly disclose inserting a printed copy of the critical information file into the hard copy of the patient record whenever the hardcopy is accessed in the healthcare provider's office.

Garcia discloses a computer system for hospital records management, wherein the paper patient chart is stored in a warehouse (col. 10 lines 1-5), and wherein a documented copy of patient information recorded electronically is included within each

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paper patient chart when the chart is retrieved from storage at the healthcare provider's location (col. 6 lines 10-12 and col. 32 lines 33-38).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features of Garcia within Eberhardt's method with the motivation of allowing a health care specialist to quickly ascertain important facts about a patient, such as in an emergency (Eberhardt, col. 7 lines 56-60), providing accurate, up to date, medical information (Eberhardt, col. 3 lines 26-30), and more efficiently and easily displaying patient information (Garcia, col. 2 lines 23-47).

Eberhardt and Garcia fail to expressly disclose whenever a patient interacts with the healthcare provider's office, executing a drug interaction screening program using information recorded about currently prescribed medications and allergies for a patient. Sujansky discloses a drug prescription assistance program in a physician's office integrated with an electronic medical records system to detect drug-drug and drug-allergy interactions based on prescription information and other clinical data (pg. 4 par. 2-3).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include Sujansky's program within the method taught collectively by Eberhardt and Garcia with the motivation of avoiding adverse drug reactions, inappropriate drug selections, and inappropriate dosing (Sujansky, pg. 4 par. 2-3).

Response to Arguments

9. Since Applicant fails to provide any arguments in the response filed 16 June 2003, the Examiner respectfully submits that rejections are maintained in view of the applied prior art for the reasons provided above (see sections 6-8), and incorporated herein.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Bleck whose telephone number is (703) 305-3981. The Examiner can normally be reached on Monday-Thursday, 8:00am – 5:30pm, and from 8:30am – 5:00pm on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached at (703) 305-9588.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist whose telephone number is (703) 306-1113.

11. **Any response to this action should be mailed to:**

Commissioner of Patents and Trademarks
Washington, D.C. 20231

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Or faxed to:

(703)-872-9306 [Official communications; including After Final communications labeled "Box AF"]

(703) 746-8374 [Informal/ Draft communications, labeled
"PROPOSED" or "DRAFT"]

Hand-delivered responses should be brought to Crystal Park 5, 2451 Crystal Drive,
Arlington, VA, 7th Floor (Receptionist).

CB

CB

July 31, 2003


JOSEPH THOMAS
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